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Date: April 15, 2005

By: J. Archer

Attorney Docket No. 100725-47 (KGB)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT : Jost SEIBLER et al  
 SERIAL NO. : To Be Assigned [This is a 371 of PCT/EP2003/011233]  
 CUSTOMER NO. : 27384  
 FILED : Herewith  
 FOR : siRNA MEDIATED GENE SILENCING IN TRANSGENIC ANIMALS  
 ART UNIT : To Be Assigned  
 EXAMINER : To Be Assigned

Commissioner for Patents  
 PO Box 1450  
 Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

SIR:

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants respectfully request that the Examiner consider the references listed on the attached Form PTO-1449.

**I. Timeliness, Fees and Certifications in lieu of Fees**

☒ A. This information disclosure statement is being filed within three months of the filing date of the application, or within three months of entry into the national stage, or before the mailing of a first Office Action on the merits. Pursuant to 37 CFR § 1.97(b), consideration of this information disclosure statement does not require a fee or a statement under 37 CFR § 1.97(e). However, should the Assistant Commissioner determine that a fee

is, in fact, due, the Assistant Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263.

☐ B. This information disclosure statement is being filed after the period in A above, but before the mailing of either a final action or a notice of allowance. Pursuant to 37 CFR § 1.97(c), consideration of this information disclosure statement requires a fee or a statement under 37 CFR § 1.97(e):

☐ 1. The Assistant Commissioner is hereby authorized to charge the fee set forth in 37 CFR § 1.17(p) to Deposit Account No. 14-1263.

☐ 2. Applicants hereby state that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ 3. Applicants hereby state that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 CFR § 1.56 more than three months prior to the filing of this information disclosure statement.

☐ C. This information disclosure statement is being filed after the period specified in B above, but on or before the payment of the issue fee. Pursuant to 37 CFR § 1.97(d), consideration of this information disclosure statement requires a petition, which Applicants hereby request, and payment of the petition fee, which is set forth in 37 CFR § 1.17(i), and which the Assistant Commissioner is hereby authorized to charge to Deposit Account No. 14-1263. Consideration of this information disclosure statement also requires a statement under 37 CFR § 1.97(e):

☐ 1. Applicants hereby state that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent

office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ 2. Applicants hereby state that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 CFR § 1.56 more than three months prior to the filing of this information disclosure statement.

## II. Copies of Listed References

☐ A. Copies of all references listed on the attached Form PTO-1449 are being supplied. Copies of U.S. patents are not included pursuant to Pre-OG Notice dated July 11, 2003.

☐ B. Copies of all references listed on the attached Form PTO-1449 have already been supplied during the prosecution of prior application Serial No. \_\_\_\_, filed \_\_\_\_, from which the present application claims priority pursuant to 35 USC § 120. Therefore, pursuant to 37 CFR § 1.98(d), copies of the references listed on the attached Form PTO-1449 are not now being supplied.

☒ C. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and the copies of the references listed on the attached Form PTO-1449 are in this national stage file. Therefore, copies of the references listed on the attached Form PTO-1449 are not now being supplied.

## III. Concise Statement of Relevance

☐ A. All references listed on the attached Form PTO-1449 are in the English language, and, therefore, a concise statement of relevance is not required.

☐ B. All references listed on the attached Form PTO-1449 are referred to in the specification and/or were cited in the international search report, and a copy of that search report, which indicates the degree of relevance found by the Search Authority, is attached.

The Examiner will note that English language counterparts or Abstracts of non-English language references are also enclosed, as follows:

- ☐ C. All references listed on the attached Form PTO-1449 were cited in the search report issued by the \_\_\_\_\_ Patent Office, and an English-language version of that search report, which indicates the degree of relevance found by that Patent Office, is attached.
- ☒ D. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and a copy of that search report, which indicates the degree of relevance found by the International Search Authority, is attached.
- ☐ E. All listed on the attached Form PTO 1449 were cited during the prosecution of the prior application indicated above under II.B.

#### **IV. Additional Information**

- ☒ A. In addition to the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the following abandoned or co-pending U.S. patent applications:

10/685,837 filed October 15, 2003


[Pursuant to 37 CFR § 1.98(a)(2)(iii), copies of these applications are not being submitted.]

- ☐ B. In addition to the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the information provided on the attached sheet.

Consideration of the foregoing in relation to this application is respectfully requested.

Respectfully submitted,

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for Kurt G. Briscoe

Attorney for Applicant(s)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT'S</b> (Form PTO-1449)		Application Number	10/531347
		Filing Date:	Herewith
		First Named Inventor	Jost SEIBLER et al
		Art Unit	To Be Assigned
		Examiner Name	To Be Assigned
		Attorney Docket Number:	100725-47 (KGB)
Sheet 1 of 2			

U.S. PATENT DOCUMENTS					
Examiner's Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US -			

FOREIGN PATENT DOCUMENTS						
Examiner's Initials*	Cite No.	Foreign Patent Document Country Code <sup>2</sup> -Number <sup>2</sup> -Kind Code <sup>2</sup>	Publication Date MM-DD-YYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
/M.N./	AB	WO 03/057840	07-17-2003	Allele Biotechnology & Pharmac		
	AC					

NON PATENT LITERATURE DOCUMENTS					
Examiner's Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>4</sup>
	AD	DEVROE E & SILVER P A; "retrovirus-delivered siRNA"; BMC Technology, Biomed Central, London, August 28, 2002; pages 1-5 XP002225637			
	AE	BRUMMELKAMP T. R. et al: "Asystem for stable expressions of short interfering RNAs in mammalian cells"; American Association for the Advancement of Science, US; Vol. 296No. 5567 (2002), pages 550-553, XP002225638			
	AF	PAUL C. P et al: "Effective expression of small interfering RNA in human cells"; Nature Biotechnology, Nature Publishing US, Vol. 20, No. 5; May 2002, pages 505-508, XP001121006			
	AG	LOSTNER et al.; "Doxycycline-mediated quantitative and tissue-specific control of gene expression in transgenic mice". Proceedings of the National Academy of Sciences of USA, Vol. 93, No. 20, October 1996. Pages 10933-10938, P002110022			
	AH	BRONSON, SARA K. et al; "Single-copy transgenic mice with chosen-site integration"; Proceedings of the National Academy of Sciences of the United States, Vol. 93, No. 19; (1996), pages 9067-9072, XP002270939			
	AI	HASUWA H. et al.: "Small interfering RNA and gene silencing in transgenic mice and rats"; Febs Letters, Elsevier Science Publishers, Amsterdam, NL; Vol. 532, No. 1-2; December 4, 2002, pages 227-230, XP004395375			

EXAMINER SIGNATURE:	DATE CONSIDERED:
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT'S**

(Form PTO-1449)

Application Number	10/531347
Filing Date:	Herewith
First Named Inventor	Jost SEIBLER et al
Art Unit	To Be Assigned
Examiner Name:	To Be Assigned
Attorney Docket Number	100725-47 (KGB)

Sheet 2

of 2

**NON PATENT LITERATURE DOCUMENTS CONTINUED**

Examiner's Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>4</sup>
	AJ	KAWASAKI H. et al; "Short hairpin type of dsRNAs that are controlled by tRNA Val promoter significantly induce RNA1-mediated gene silencing in the cytoplasm of human cells"; Nucleic Acids Research, Oxford University Press, Surrey, GB; Vol. 31, No. 2, January 2003; pages 706-707, XP002965487	
	AK	MATSUKURA, SHIRO et al; "Establishment of conditional vectors for hairpin siRNA knockdowns"; Nucleic Acids Research, England, August 1, 2003; Vol. 31, No. 15, pages 1-5, XP002270940	
	AL	VAN DE WETERING, MARC et al; "Specific inhibition of gene expression using a stably integrated, inducible small-interfering-RNA vector."; Embo Reports; Vol. 4, No. 6, June 2003; pages 609-613, XP002270941	
	AM	MERLINO G T, et al; "Accurate in-vitro transcriptional initiation of the chick alpha 2 type 1 collagen gene." Journal of Biological Chemistry, Vol. 256, No. 21; 1981, pages 11251-11258, XP002270942	
	AN		
	AO		

**EXAMINER SIGNATURE:**Marcia  
Noble

/Marcia Noble/

**DATE CONSIDERED:**

07/21/2008

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPPE 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPPE 901.04. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

The collection of information is required by 37 CFR 1.197 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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